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मानक

IS 11640-1 (1986): Retractor, General Surgery, Part 1: Schonborn's Pattern [MHD 1: Surgical Instruments]









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SPECIFICATION FOR RETRACTOR, GENERAL SURGERY PART 1 SCHONBORN'S PATTERN

1. Scope — Prescribes dimensional and other requirements of Schonborn's pattern retractor used in general surgery.

2. Shape and Dimensions – As shown in Fig. 1.



All dimensions in millimetres. FIG. 1 RETRACTORS, SCHONBORN'S PATTERN

3. Material – Stainless steel conforming to designation 20Cr13 or 30Cr13 of IS: 6603-1972 'Specification for stainless steel bars and flats'.

4. Workmanship

4.1 The retractor shall be free from burrs, pits, cracks and other surface defects.

4.2 The edges of the blade shall be properly rounded and the retractor shall be free from sharp edges.

5. Surface Condition — All surfaces shall be free from pores, crevices and grinding marks. The retractor shall be supplied free from residual scale, acid, grease and grinding and polishing materials. Compliance with these requirements shall be checked by inspection using normal vision (corrected, if necessary).

5.1 Surface Finish — The surface finish shall be one of or a combination of the following:

- a) Mirror polished;
- b) Reflection-reducing, for example, satin finish, matt black finish; and
- c) An applied surface coating, for example, for insulation purposes.

Note — The satin finish should be effected by an appropriate procedure, such as grinding, brushing, electropolishing and in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth and it should reduce glare. Instrument of mirror finish should be adequately ground to remove all surface imperfections and polished to remove grinding marks, resulting in a mirror finish. The mirror finish should be effected by an appropriate procedure, such as polishing, brushing electropolishing and mirror buffing.

5.2 Passivation and Final Treatment — The retractor shall be treated by a suitable passivation process.

Note — Examples of methods of passivation are by electropolishing or by treating with 10 (v/v) nitric acid solution for not less than 30 min at a temperature of not less than 10° C and not exceeding 60° C. The retractor should then be rinsed in water and dried in hot air.

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6. Heat Treatment and Hardness — The retractor shall be heat treated to give a hardness of 380 to 430 *HV* when tested in accordance with IS : 1501-1968 'Method for Vickers hardness test for steel (*first revision*)'.

7. Tests

7.1 Flexibility Test — Hold the retractor in a suitable vice at the middle portion so that the working end protrudes outside the vice in the downward direction. Apply a force of 250 N at the retracting end and hold it for 5 minutes. After the test there shall be no damage to the retractor or take a permanent set.

7.2 Corrosion Resistance Test — Test the retractor in accordance with IS: 7531-1975 'Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments'. It shall show no sign of corrosion after the test.

8. Marking — The retractor shall be legibly and indelibly marked with the manufacturer's name, initials or recognized trade-mark and the words 'Stainless Steel'. The marking shall preferably be done by electrical etching and not by stamping.

8.1 *ISI Certification Marking* — Details available with the Indian Standards Institution.

9. Packing - As agreed to between the purchaser and the supplier.

10. Sampling — Sampling procedure and acceptance criteria for the forceps shall be as agreed to between the purchaser and the supplier. However a recommended scheme for the same is given in Appendix A.

APPENDIX A

(Clause 10)

SAMPLING PLAN AND CRITERIA FOR CONFORMITY

A-1. Lot

A-1.1 In a consignment, all the retractors of the same pattern and dimensions shall be grouped together to constitute a lot, not exceeding 50 items. Each lot shall be tested for the requirements of this specification.

A-2. Scale of Sampling and Criteria for Conformity

A-2.1 Eight retractors shall be selected at random from each lot by using random number tables (IS: 4905-1968 Methods for random sampling). Such retractor in the sample shall be individually tested for the requirements of shape and dimensions, material, workmanship, finish and marking. Any retractor failing to meet one or more of the above requirements shall be termed as defective. No defective retractors in the sample shall be permitted if the lot is to be accepted under this clause.

A-2.2 The lot which has been found satisfactory according to A-2.1 shall be tested for hardness, flexibility and corrosion resistance test. For this purpose, one retractor shall be sampled at random and tested for the above requirements. If need be, more retractors may be drawn for conducting the relevant tests.

A-2.2.1 No failure shall occur if the lot is to be declared acceptable under this clause.

EXPLANATORY NOTE

Considerable assistance has been derived from DIN 13464-1982 Medical instrument; retractor, Schonborn type, issued by Deutsches Institut für Normung (West Germany).